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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/936,271 | 09/10/2001 | George M Yousef | MTS3USA | 2550 |

270 7590 08/13/2003

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| EXAMINER |
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QIAN, CELINE X

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 08/13/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,271

Applicant(s)

YOUSEF ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,32,33,35-37,39,44 and 46 is/are pending in the application.

4a) Of the above claim(s) 46 is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,32,33,35-37,39 and 44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9,14 6) ☐ Other:

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DETAILED ACTION

Claims 1, 32, 33, 35-37, 39, 44 and 46 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 13 is acknowledged.

During a telephone conversation with Applicant's representative Mary Bak on 8/1/03, Applicants further elect the invention drawn to SEQ ID NO:13 for examination. Affirmation of this election must be made by applicant in replying to this Office action. Claim 46 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1, 32, 33, 35-37, 39 and 44 are currently under examination.

Claim Objections

Claim 44 is objected to for containing non-elected subject matter. Claim 44 recites a composition comprising a protein, which belongs to the invention of Group II. Amending the claims such that they are only directed to elected inventions is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 32, 33, 35-37, 39 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . . [emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claim 1 is drawn to an isolated KLK-L2 nucleic acid molecule that is at least 30 nucleotides in length which hybridizes to SEQ ID NO:13. The claim encompasses potentially a large genus of nucleic acid molecules of various size ranging from 30 base pair to infinity. The specification only discloses one KLK-L2 protein having the genomic sequence of SEQ ID NO:13. The specification fails to disclose any other nucleic acids of various sizes that hybridize to SEQ ID NO:13 encode the KLK-L2 protein which possesses serine protease function. As such, the structural functional relationship between the claimed nucleic acid molecule and its function as a serine protease is missing. Therefore, the written description requirement is not met.

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Claim 32 is drawn to an isolated KLK-L2 molecule that comprises a nucleic acid sequence encoding a protein having substantial sequence identity with SEQ ID NO:14, a complementary sequence to said nucleic acid molecule, a degenerate form of said nucleic acid sequence, a nucleic acid sequence capable of hybridizing to said sequence, a nucleic acid encoding a truncation, analog, allelic or species variation of KLK-L2 protein. The claim encompasses a vast genus of nucleic acid molecules of various size, sequences that may not relate to nucleic acid encoding KLK-L2 protein. The specification only discloses one KLK-L2 nucleic acid sequence. The specification fails to disclose any other KLK-L2 nucleic acid that hybridizes to a sequence encoding a amino acid that share substantial sequence identity encoding SEQ ID NO:14, a complementary sequence to a sequence sharing substantial identity to SEQ ID NO:14, a degenerate form of said sequence, truncation, analog, allelic or species variation of said sequence. As such, the structural functional relationship between the claimed nucleic acid and its function as a serine protease is missing. Therefore, the written description requirement is not met.

Similarly, claim 33 is drawn to an isolated KLK-L2 nucleic acid comprises a nucleic acid sequence complementary to a region of SEQ ID NO:13, a nucleic acid capable of hybridizing to said nucleic acid, or a degenerate form of said nucleic acid sequence. The claim encompasses a vast genus of nucleic acid molecule of different size which may or may not relate to nucleic acid encoding KLK-L2 protein. The specification fails to disclose any of the claimed nucleic acid except a nucleic acid encoding KLK-L2 protein in human. Therefore, the specification neither describes a representative number of species by their complete structure nor their other identifying characteristics. As such, the inventors fail to describe the invention in such a way to

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convey a skilled artisan that the inventors had possession of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 35, 36, 39 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 32, 35, 36 and 39, the recitation of "having substantial sequence identity" renders the claims indefinite because the specification does not disclose what percentage of sequence identity is "substantial." As such, the metes and bounds of the claims cannot be established.

Claim 44 recites the limitation "a substance or compound identified by the method of 37" in line 5. There is insufficient antecedent basis for this limitation in the claim. Claim 37 is directed to a method of preparing a protein. It does not recite substance or compound identified by any method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 33 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (accession number N80762).

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Hillier et al. disclose a 441 base pair nucleic acid sequence that is capable of hybridizing to SEQ ID NO:13 under stringent condition. Therefore, Hillier et al. disclose the instantly claimed invention.

Claims 32 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (accession number W73168).

Hillier et al. disclose a 498 base pair nucleic acid encodes a protein that share substantial sequence identity with SEQ ID NO:14. Therefore, Hillier et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al.

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The teaching of Hillier et al. was discussed above. However, Hillier et al. do not teach a vector comprising the claimed sequence, a host comprising said vector and a method of preparing a protein by culturing said host cell.

It would have been obvious to one of ordinary skill of art to make a vector comprising the isolated nucleic acid as claimed, and introduce said vector to a host cell to express the protein encoded by the nucleic acid. DNA cloning and expressing protein *in vitro* is well known method in the field of molecular cloning and gene expression. Absent evidence to the contrary, one of ordinary skill of art would have reasonable expectation of success to insert the nucleic acid molecule into a vector, transforming the vector to a host cell for protein expression, and isolate protein from the host cell. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

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Celine Qian, Ph.D.

August 8, 2003